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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

DAVID S. GROSS,

Case No. 3:23-cv-00093

Plaintiff,

v.

**COMPLAINT FOR VIOLATIONS  
OF SECTIONS 14(d), 14(e) AND  
20(a) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

CHEMBIO DIAGNOSTICS, INC.,  
KATHERINE L. DAVIS, JOHN G.  
POTTHOFF, DAVID W.K.  
ACHESON, DAVID W. BESPALKO,  
RICHARD L. EBERLY, LESLIE  
TESO-LICHTMAN, and LAWRENCE  
J. STEENVOORDEN.

**JURY TRIAL DEMAND**

Defendants.

**COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

Plaintiff David S. Gross ("Plaintiff"), alleges as follows based (i) upon personal knowledge with respect to himself and his own acts, and (ii) upon information and belief as to all other matters based on the investigation conducted by himself, which included, among other things, a review of the relevant U.S.

Securities and Exchange Commission (“SEC”) filings, and other publicly available information.

### **NATURE OF THE ACTION**

NOTE: The text #1, #2, #3, and #4 in this section "NATURE OF THE ACTION" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

1. The action is brought by Plaintiff against Chembio Diagnostics, Inc. (“Chembio” or the “Company”) and the members of the Company’s board of directors (“Board”) for violations of (i) Sections 14(d), 14(e), and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. § 78n(d), § 78n(e) and § 78t(a), and (ii) CFR § 240.14d-101. Plaintiff’s claims arise in connection with the Board’s recommendation that the stockholders of the Company (“Chembio Stockholders”) tender their shares to an affiliate of Biosynex SA, (“Biosynex”), pursuant to a tender offer (“Tender Offer”) to acquire all of the issued and outstanding shares of Chembio for \$0.45 in cash per share (“Merger Consideration”).

2. On January 31, 2023, Chembio and Biosynex announced that they had entered into an agreement (“Merger Agreement”) providing for Biosynex to

purchase all of the outstanding shares of Chembio for the Merger Consideration via the Tender Offer.

3. On February 14, 2023, Biosynex commenced the Tender Offer by filing a Tender Offer Statement TO (“TO Statement”) with the SEC. The TO Statement provides that the Tender Offer expires one minute after 11:59 P.M. Eastern Time on March 14, 2023 (“Expiration Date”), unless extended or earlier terminated in accordance with the Merger Agreement. Upon satisfaction of various conditions described in the TO Statement, and consummation of the Tender Offer, Chembio will survive as a wholly-owned subsidiary of Biosynex under Nevada law pursuant to a series of merger transactions (“Merger”).

4. On February 14, 2023 Defendants filed a materially false and misleading Schedule 14D-9 Solicitation/Recommendation Statement (“Recommendation Statement”) with the SEC recommending that Chembio Stockholders tender their shares to Biosynex pursuant to the Tender Offer. As detailed below, the material misrepresentations and omissions in the Recommendation Statement render it false and misleading in violation of the above-referenced Exchange Act provisions.

5. It is imperative that such violations are promptly cured to enable Chembio Stockholders to make an informed decision concerning whether to tender their shares to Biosynex before the Expiration Date. Therefore, Plaintiff seeks to enjoin Defendants from closing the Tender Offer and/or taking any steps to consummate the Merger, until such violations are cured. Furthermore, Plaintiff

would like to cross-examine Chembio's response with responses received by various Federal agencies involved with Defendants. To that extent, until Plaintiff receives and deems satisfactory Freedom of Information Act (FOIA) responses from government agencies closely involved with Defendants: namely the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), particularly the Office of Biomedical Advanced Research and Development Authority (BARDA), The Department of Health and Human Services (HHS), the Defense Health Agency (DHA) or any other DoD branch involved with Chembio, the Department of Veterans Affairs (VA), or any other Federal government agency deemed potentially appropriate by Plaintiff, it will be hard if not impossible to make an informed decision with cross-examining concerning whether to tender their shares to Biosynex before the Expiration Date; unless the violations are cured with exceptional records produced by Defendants that fully include these Federal agencies by Defendants. Alternatively, if the Tender is closed and the Merger is consummated, Plaintiff reserves the right to recover damages suffered by himself as a result of such violations.

### **JURISDICTION AND VENUE**

NOTE: The text #6 and #7 of "JURISDICTION AND VENUE" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al.

Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

6. This Court has subject matter jurisdiction over the claims asserted herein for violations of Sections 14(d), 14(e) and 20(a) of the Exchange Act pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331 (federal question jurisdiction).

7. This Court has personal jurisdiction over each of the Defendants because each defendant has sufficient minimum contacts with the United States so as to make the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice. *See Moon Joo Yu v. Premiere Power LLC*, No. 14 CIV. 7588 KPF, 2015 WL 4629495, at \*5 (S.D.N.Y. Aug. 4, 2015) (because Exchange Act provides for nationwide service of process, and Defendant resides within the United States, and conducts business within the United States, he should reasonably anticipate being haled into court in the United States, and Court's exercise of personal jurisdiction over Defendant with respect to Plaintiffs' securities fraud claim is proper); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, No. 11 MDL 2262 NRB, 2015 WL 6243526, at \*23 (S.D.N.Y. Oct. 20, 2015) ("[w]hen the jurisdictional issue flows from a federal statutory grant that authorizes suit under federal-question jurisdiction and nationwide service of

process . . . Second Circuit has consistently held that the minimum-contacts test in such circumstances looks to contacts with the entire United States rather than with the forum state.”).

8. Venue is proper under 28 U.S.C. § 1391(b) because Defendants transact business in this District. In particular, Chembio is incorporated in this District and the Merger will be affected in this District in accordance with Nevada Revised Statutes (“NRS”) Section 92A.133. Further, as stated in the Tender Offer, Project Merci Merger Sub, Inc. ("Purchaser") is a Nevada corporation.

### **PARTIES**

9. Plaintiff has been a continuous stockholder of Chembio stock since May 2021.

10. Defendant Chembio is a Nevada corporation with its principle executive offices located at 3661 Horseblock Road, Medford, New York 11763.

11. Defendant Katherine L. Davis has been Chair of the Board and served as a director of the Company at all relevant times.

12. Defendant John G. Potthoff, Ph.D., has served as a director of the Company at all relevant times.

13. Defendant David W.K. Acheson, M.D., has served as a director of the Company at all relevant times.

14. Defendant David W. Bepalko has served as a director of the Company at all relevant times.

15. Defendant Richard L. Eberly currently serves as the President and Chief Executive Officer (“CEO”) of the Company, and has served as a director of the Company at all relevant times.

16. Defendant Leslie Teso-Lichtman has served as a director of the Company at some relevant times.

17. Defendant Lawrence J. Steenvoorden currently serves as the Company’s Chief Financial Officer. Defendant Steenvoorden personally signed the Recommendation Statement.

18. Defendants identified in paragraphs 11 to 17 are collectively referred to herein as the “Individual Defendants,” and together with Chembio, collectively, the “Defendants.”

## **SUBSTANTIVE ALLEGATIONS**

### ***Company Background***

19. Based on Chembio's January 2023 Corporate Presentation / Investor Deck in the Investor Relations section of Chembio's website (<https://chembio.com/>):

Chembio develops and commercializes high-quality point-of-care and OTC diagnostic tests for the rapid detection and diagnosis of infectious diseases that provide results in approximately 15 minutes using fingertip blood, nasal swabs, and other sample types.

Chembio has 3 Core Product Technologies:

- DPP (Dual-Path Platform) Point-of-Care
- SURE CHECK Self-Test OTC (Recent OTC launches in Europe, UK & Brazil and pursuing U.S. OTC, \$635 Million HIV point-of-care market cited by Chembio / Insight Partners, The SURE CHECK Self-Test OTC product is in over 40,000 international pharmacies.)
- STAT-PAK Point-of Care (HIV, Chagas)

Chembio has 211 employees worldwide, 23 issued U.S. patents, some number of pending U.S. patents, and 80+ distribution partners.

Pre-2020, the Company's broad portfolio of infectious disease products was focused principally on sexually transmitted disease and fever & tropical disease in high volume and low margin markets.



From 2020-2021, the Company shifted "substantially all" resources to leverage the DPP technology platform to address the acute & escalating need for diagnostic testing for COVID-19.

From 2022 and on, the Company cites an "exciting future" framed around extracting value from DPP technology for anticipated higher-value point-of-care assays in developed markets, SURE CHECK platform for developing OTC markets, and executing the "Global Competitive Program (GCP)".

In the USA, Chembio has products labeled:

- DPP SARS-CoV-2 Ag (FDA EUA pending)
- DPP HIV-Syphilis System (CLIA Waiver pending at date of the Tender Offer, now CLIA approved)
- DPP HIV 1/2
- SURE CHECK HIV 1/2 Self Test (US in development, but past feasibility status)
- HIV 1/2 STAT-PAK
- DPP Zika IgM
- DPP Ebola Antigen (EUA)
- DPP Cervid TB
- DPP Elephant TB

In Latin America (labeled LATAM) Chembio has products labeled:

- DPP SARS-CoV-2 Antigen (approved by ANVISA, CE mark, SAPHRA),
- DPP SARVS-CoV-2 Ag Self-Test (pending approval by ANVISA, CE Mark)
- DPP COVID-19 IgM/IgG System (approved by CE Mark)
- DPP Respiratory Antigen Panel (approved by CE Mark, ANVISA)
- DPP HIV-1/2 Assay
- SURE CHECK HIV 1/2 Assay
- HIV 1/2 STAT-PAK Assay
- SURE CHECK HIV Self-Test (approved by WHO, CE, ANVISA, UK Southeast Asia)
- Chagas STAT-PAK
- DPP HIV-Syphilis System
- DPP Syphilis Screen & Confirm Assay
- DPP Zika IgM/IgG System
- DPP ZCD IgM/IgG System
- DPP Dengue NS1 Antigen System
- DPP Dengue IgM/IgG System
- DPP Chikungunya System
- DPP Leishmaniasis Assay
- DPP Confirmatory Assay
- DPP Microreader.

In Europe, the Middle East, and Asia (labeled EMEA & Asia) Chembio has products labeled:

- DPP SARS-CoV-2 Antigen
- DPP SARS-COV-2 IgM/IgG
- DPP Respiratory Antigen Panel
- STAT-VIEW HIV 1/2 Assay
- SURE CHECK HIV 1/2 Assay
- HIV 1/2 STAT-PAK Assay
- SURE CHECK HIV Self-Test
- DPP HIV 1 Assay, DPP HIV-Syphilis
- DPP Syphilis Screen & Confirm Assay
- DPP Zika IgM/IgG System
- DPP ZCD IgM/IgG System
- DPP Dengue Combo
- Chagas STAT-PAK Assay
- DPP Microreader
- DPP Microreader II

Not related to any specific region, Chembio has products labeled:

- DPP Syphilis TnT (Feasibility underway)

- DPP Lyme IgM/IgG (Feasibility underway)

Additionally, Chembio has a business relationship with InBios for a branded "STATUS" COVID-19 diagnostic antigen respiratory panel that is not listed in the Investor Deck.

***Background to the Merger With Biosynex***

NOTE: The text in this section "Background to the Merger with BioSynex" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

20. On April 22, 2022, at a meeting of the Board, one of the Company's financial advisors, Craig-Hallum Capital Group LLC ("Craig-Hallum"), recommended the Company pursue a strategic sales process in light of ongoing regulatory, operational and liquidity challenges. Craig- Hallum reviewed a list of potential acquirers. After hearing Craig-Hallum's recommendations, the Board decided to retain Craig-Hallum to pursue a potential sale or other strategic transaction (which the Board referred to as "Project Cheetah").

21. During May 2022, Craig-Hallum engaged in broad outreach to potential strategic partners for the Company that Craig-Hallum viewed as most

likely to be interested in and able to engage in a possible strategic transaction with the Company. Defendant Eberly solicited input from and provided the members of the Board and the Business Strategy Committee of the Board (the “Strategic Committee”) with periodic updates regarding Project Cheetah throughout the process. Following Craig-Hallum’s initial outreach, the Company entered into confidentiality and non-disclosure agreements (“NDAs”) with three potential acquirers on May 25, 2022, including Biosynex.

22. During the week of June 27, 2022, members of the Company’s management met with Biosynex to discuss the operational benefits associated with a potential transaction.

23. On July 19, 2022, Craig-Hallum informed the Strategic Committee that Biosynex was not interested in pursuing an acquisition of the Company at the time, but was preliminarily considering a potential purchase of or investment in the Company’s wholly-owned German subsidiary, and a license agreement for the Company’s DPP technology.

24. On November 8, 2022, the Company and Party A entered into a non-binding term sheet for the acquisition of the Company by Party A (the “Party A Non-Binding Term Sheet”) in a one step merger transaction. The Party A Non-Binding Term Sheet contemplated the acquisition of all of the outstanding shares of

the Company for an initial price of \$0.42 per share to be reduced by certain sums. The Company preliminarily estimated that the Company's stockholders would potentially receive between \$0.20 and \$0.30 per share in connection with such transaction depending upon the timing of closing and the actual amount of the reductions. The Party A Non- Binding Term Sheet also included a 30-day exclusivity period.

25. During the week of November 28, 2022, however, Party A advised the Company that it no longer wished to pursue a one-step merger transaction as originally contemplated, and demanded interim commercial arrangements in advance of any potential transaction.

26. On December 8, 2022, following the expiration of the Company's exclusivity with Party A, the Company's senior management contacted Biosynex to discuss a potential strategic transaction.

27. On December 15, 2022, following further discussion between the parties, Biosynex sent the Company a non-binding term sheet providing for the acquisition of the Company for between \$0.40 and \$0.45 per share in cash.

28. Later on December 15, 2022, the Company advised Party A that the Company was not interested in proceeding with any sort of interim commercial arrangements followed by a potential acquisition of the Company, but that it would

be interested in a possible sale transaction at \$0.42 per share with no adjustments. Party A never responded to such proposal.

29. On December 16, 2022, the Company executed the non-binding term sheet with Biosynex providing for the acquisition of the Company for between \$0.40 and \$0.45 per share in cash through a tender offer for a majority of the outstanding shares followed by a short-form merger under Nevada law. The term sheet contained an exclusivity period until January 31, 2023.

30. On January 27, 2023, after further discussions between the Company and Biosynex, and due diligence by Biosynex, the Company and Biosynex agreed to a price of \$0.45 per share in cash.

31. On January 31, 2023, Craig-Hallum provided its opinion (“Fairness Opinion”) to the Board that the Merger Consideration was fair from a financial point of view to Chembio Stockholders. The Board thereafter unanimously determined that the Merger and related transactions were in the best interests of the Company and its stockholders, and resolved to recommend that Chembio Stockholders tender their Shares to Biosynex pursuant to the Tender Offer.

32. On January 31, 2023, the Company and Biosynex issued a joint press release announcing the transaction.





***The Recommendation Statement Contains Material Omissions That Render Statements Therein Misleading***

33. Defendants disseminated a false and misleading Recommendation Statement to Chembio Stockholders that misrepresents or omits material information that is necessary for Chembio Stockholders to make an informed decision concerning whether to tender their shares to Biosynex pursuant to the Tender Offer

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Why Chembio Chose To Switch All Resources to COVID-19 Rather Than Their Existing Product Mix***

34. What were the revenue projections for the next five years (2020, 2021, 2022, 2023, 2024) for the other non-COVID related product mix prior to Chembio shifting "substantially all" of their resources to COVID-19 during the 2020-2021 year (Chembio Corporate Presentation / Investor Deck / January 2023)?

***Material Nondisclosures Concerning the Lack of Books, Records and Accounts of Contact in the Tender Offer RE: Chembio's Utilization of the Small Business***

***Administration's Paycheck Protection Program (PPP) To Financially Grow  
Through Manual Labor and its Impact on Chembio Test Production  
Automation, Employee Reorganizations, and Profitability***

35. Background: April 29, 2020: Source: "Loopholes In Small Business Relief Program Allow Thriving Companies To Cash In" [NPR News] ... When officials with Chembio Diagnostics heard about the Small Business Administration's Paycheck Protection Program, they jumped at the chance to get a share of the public money. And they got it: nearly \$3 million. The Long Island, N.Y.-based company, which also has offices in Berlin and Brazil, develops and manufactures infectious disease tests. Its work includes tests for HIV, Ebola and Zika. Earlier this month, company officials announced that they got emergency approval from the FDA to use a rapid COVID-19 test. That created a huge business opportunity for them. Their stock price went from an average of about \$5 a share last year to about \$11 this week. The paycheck protection loan was the liquidity the company needed to help grow. "For us to be able to increase our manufacturing capabilities, we thought that having this supplemental dollar amount or loan would be very helpful ... in helping us," says Gail Page, a Chembio board member and former interim CEO. "When you get these pandemics, then there's all of a sudden this big rush and you need to be able to supply."(<https://www.wbur.org/npr/>

847582203/loopholes-in-small-business-relief-program-allowed-thriving-companies-to-cash-in)

36. Eberly August 4, 2022: "To further increase margins and profitability, we are currently finalizing our two main initiatives to increase efficiency. First, we are continuing our automation expansion, which should reduce labor requirements and result in lower manufacturing costs."

37. May 17, 2022: Chembio... today announced it has entered into a manufacturing agreement with Reszon Diagnostics International Sdn May 2020 Bhd. (Reszon) to produce Chembio's HIV 1/2 STAT-PAK Assay products in the Chembio Diagnostics Malaysia (CDM) facility. CDM had previously suspended operations in May 2020. Reszon is actively transforming its manufacturing process to full automation in order to competitively address growing global needs. Reszon is also committed to providing the best affordable diagnostics in the self-testing sector. (<https://chembio.com/chembio-diagnostics-announces-agreement-for-reszon-diagnostics-international-to-manufacture-chembios-hiv-1-2-stat-pak-assay-at-chembio-diagnostics-malaysia-facility/>)

38. Analyst Bruce Jackson May 5, 2022: "Okay. All right. One last question for me and then I'll hop back in queue. It's about the -- your

manufacturing. It's a flexible arrangement. You've got both some automation and some manual lines. Is the automation set up for any particular product, or can you swap the different product lines in and out?

Eberly: "Yes. Our goal Bruce is to have automation capability for every product format we have which that includes our DPP platform, our DPP multiplex platform, as well as our SURE CHECK HIV self-test platform, as well as our STAT-PAK HIV platform. So that's our goal. So we have built into that strategy a lot of flexibility in terms of production of those product formats on automation options. The only thing I would say in addition to that Bruce is that, because of the regulatory approvals that we have around the world including FDA, WHO, ANVISA in Brazil, CE Mark for Europe, we do have to go through in some cases a validation and registration of a change in production. So the bottom line is we're maximizing though every bit of opportunity to automate or manufacturing."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: The FDA and NIH's Cross-Reactivity Required Targets During the COVID-19 EUA Review Cycle and Omitted Cross-Reactivity Required Targets For the Original Failed EUA Panel***

39. 9 August 2020: "Analyst Kyle Bauser: Okay. So I guess, just for clarity, so the competitors that also targeted nucleocapsid initially that did achieve favorable results. Was that a function of them just doing internal validation with a larger sample size? I guess I'm just a little confused about how those companies were able to use that target and still kick out acceptable accuracies.

Eberly: So Kyle, we do stand by our original clinical data that we submitted to the EUA or to the FDA for EUA. So I can't speak for other competitors in terms of what they did and how they designed their assays. But I think the point is that we decided we're going to revise the system and to ensure that when we are evaluated by the NCI, that we have great assurance that we're going to pass the NCI study evaluation."

Bauser: Got it. Okay. And maybe just switching a little bit, but on the same application, how have you been addressing the cross reactivity issue of that test as well? I mean, if we move on from the spike protein. It looked like the cross reactivity with HIV was quite high, which was surprising since HIV assays are Chembio's bread and butter. So kind of what happened there? And are you confident that 40% reactivity number will come down?

Eberly: Yes, Kyle. I can't speak to the cross reactivity from the original assay at this point. But in terms of the revised assay that we have - that we're in the process of completing development, we have done extensive cross reactivity studies, not only for HIV, but for also all the other required targets for a EUA submission.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Priority-Review Decision Making or Quarterly Changes to Public Policy at the FDA or CDC Regarding Antibody or Antigen Tests***

40. Nothing further to add as stated above

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Official FDA Documents or Emails Stating that the DPP Technology's Relatively Limited Impact on Testing Accessibility or Testing Capacity was what triggered the De-Prioritization, and Not Potentially Other Unspecified Factors, and What Supplemental Info Was Precisely Requested and When?***

41. Specifically what supplemental info was requested by the FDA and on what specific timeline? What language did the FDA use in these "de-

prioritization" and "declines to review"? What evaluations were done by Chembio to decide whether to resubmit the EUA application? Why was a timeline seemingly agreed upon between the FDA and Chembio, only for Chembio to report the FDA never reviewed the relevant test? What accounts of contact made Chembio so confident they had a plan if they could not offer guidance?

Eberly, March 12, 2021: "Now I'd like to provide an update on our regulatory filings in the U.S. In the U.S. we submitted EUA applications for our COVID-19 antibody test in September of 2020 and our COVID-19 antigen test in October 2020. We completed the development of these tests and submitted their respective EUAs ahead of the timelines we had communicated. In December 2020, the FDA notified us that it was declining to review the COVID-19 antibody test based on the FDA's then-effective prioritization guidance. Under this guidance, review of the system was not a priority for the FDA, because for example, the FDA determined that authorization of the test would have relatively limited impact on testing accessibility or testing capacity. The FDA has supplementally advised us of the type and nature of information it would need to receive in a subsequent EUA application in order for the COVID-19 antibody tests to be prioritized for review. To be clear, our COVID 19 antibody test was not reviewed by the FDA. We believe the application that we submitted, included data that met the performance requirements laid out by the agency ... We are continuing to evaluate whether to

commit further resources to the testing and development that would be required in order to submit our new FDA EUA application for COVID-19 antibody test systems ... Turning back for a COVID-19 antigen test. In January 2021, the FDA notified us that it was declining to review the COVID-19 antigen test based on its updated prioritization guidance, under which reviewing the system was not a priority. The FDA has supplementally advised us at the type of nature of information it would need to receive in a subsequent EUA application in order for our COVID-19 antigen tests to be prioritized for review. And we were engaged in testing and development in order to submit a new EUA application. We appreciate the FDA's guidance and BARDA's continued support and we are completely committed to gathering this specific information required ... We are confident we have a plan. The resources and technical capability required to resubmit the EUA ... We will not be providing guidance regarding the end of the timeline or achievement of the resubmission, based on the uncertainty of the changing regulatory process and priorities. We look forward to sharing news about any FDA or regulatory awards in due course ... Regarding the pursuit of 510(k) clearance from the FDA for the DPP SARS-CoV-2 antigen system. These clinical trials are also ongoing. The timeline for the trials and our achievement of related milestones were delayed by the evolving U.S. populations with low COVID-19 positivity rates triggered by vaccination rollouts, the impact of those evolving populations on the rate of enrolling subjects, the absence of guidance from the FDA regarding how to



treat low positivity rates within a clinical study and the FDA's as yet unissued 510(k) guidance regarding COVID-19 antigen tests."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: COVID-19 Antibody (Serological) IgM/IgG and Antigen Varying Numerical Levels for COVID-19 / SARS-CoV-2 Detection, To Inform Prognosis or Infection Progression, or For Vaccine Development, Testing, Quality Control, etc. or For Antibody Drug Development, Oral Drug Development, or Development of Other Therapeutics for COVID-19***

42. How exactly did numerical antibody test results or otherwise numerical test results (rather than a simple positive / negative), intend to help alleviate the above COVID-19 public health issues? What records show a supposed competitive advantage by numerically analyzing these antibody and potentially antigen counts? What customers did Chembio intend to "pick-up" by offering this more detailed test, and what revenue gain was expected over just offering a simple positive/negative test? Did Chembio formally intend to pick up therapeutics manufacturers as potential customers rather than just targeting the general public? Otherwise, what was the purpose of Chembio's efforts with Renaissance School of Medicine at Stony Brook University Material Chembio never provided specific

examples of what competitive advantage would be gained other than convalescent plasma therapy, and it seems like for their EUA submissions, these numerical results were not needed, and could have created an overly-complex situation for the FDA to analyze.

43. Important Project with the Renaissance School of Medicine at Stony Brook University Material ... Nondisclosures about the use of Chembio's Research into Convalescent Plasma as a Treatment for COVID-19.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: BARDA's Recommended Multiplex Respiratory Panels to Chembio and Other Antibody (Serological)/Antigen Testing Companies that Should Differentiate Between COVID-19/SARS-CoV-2 and Influenza A, Influenza B, and Potentially RSV, etc. Despite There Being No Realistic Timetable for Approval or Way of Achieving this Test Quickly That Was Scientifically Sound or Fiducially Sound for Chembio Shareholders.***

44. What are all the FDA's other review priorities for the time table in question where the CDC was concerned about Influenza A, Influenza B, and RSV?

45. What specifically was learned about the virus and testing landscape that impacted Chembio's antibody and antigen test offerings?

46. What reasons did BARDA give as to why it thought the DPP technology was strong for a respiratory panel?

47. Eberly, 7 August 2021: "We are working to finalize EUA submission materials for the DPP respiratory antigen panel internally and with BARDA. The FDA has the pathway for manufacturers such as Chembio that do not have a prior 510(k) approved influenza test.

We are not, however, aware of the FDA having awarded to any such manufacturer an EUA for an influenza test, and the FDA may not consider the review of our EUA application for the DPP respiratory antigen panel as a priority and therefore, may decline to review the EUA application. That said, we are optimistic about the market opportunity for our DPP respiratory panel. In late July, the CDC issued guidance that incurred us clinicians to choose a multiplex test that can be used to detect and differentiate SARS-CoV-2 from influenza viruses. That is precisely what the DPP respiratory panel was designed to achieve. This past year's flu season was almost nonexistent ... Now with much of the global economy reopened at immunity to flu viruses weakened due to a minor flu season last year, the CDC is preparing for flu virus circulation to return to pre-pandemic levels given that the circulation of some respiratory viruses is already returning to pre-pandemic levels, potentially making such multiplex test valuable tools when evaluating patients suspect of COVID-19 and/or the flu. This is consistent with our thinking that

infection identification will be even more critical as closes on approaches because the infections present with similar symptoms, but the treatment and management protocols differ greatly. We hope to be able to position the DPP respiratory antigen panel as a critical component in managing the pandemic through the respiratory infection season and as the pandemic evolves, either with additional variants or into an endemic stage.

As a reminder, COV virus DPP respiratory panel is designed, when used in connection with the DPP Micro Reader optical analyzer to provide simultaneous discrete and differential detection to SARS-CoV-2, influenza A, influenza B antigens from a simple nasal swab at about 20 minutes. The test system is intended to enable appropriate clinical management of patients with suspected respiratory infections and assist in the containment of COVID-19 cases during the flu season.

Moving on to the DPP SARS-CoV-2 antigen test system. The FDA notified us in June 2021 that it was again declining to review the EUA submission for the test based on the FDA's effective prioritization guidance. Under which reviews and test is it was not a priority because of the anticipated resources needed by the FDA to continue a review of our EUA request. The volume of the EUA request the FDA had received and a variety of other factors. Similar to the respiratory panel, our clinical trials and the related timeline and achievement of related milestones are

under the initial BARDA Award for the DPP SARS-CoV-2 antigen test system were delayed by the same factors that I outlined earlier on the call. The effects of a changing population of COVID-19 infection rates were reflected in our clinical results and created complexities and the data submitted to the FDA in connection with the EUA application for the DPP SARS-CoV-2 antigen test system.

As a result, in June 2021, we worked with BARDA to extend the initial awards contract period of performance at no additional cost at part in order to provide us the opportunity to submit a new EUA to the FDA to address the FDA's additional priorities and incorporate additional data collected from international populations with higher positivity rates.

We are in the process of collecting such samples in order to address the complexities in our data set that we believe resulted in the FDA's decision to deprioritize our second EUA application. We then intend to incorporate the collected samples in our clinical data for a new EUA application for the DPP SARS-CoV-2 antigen test system. There can be no assurance that the FDA will prioritize the review of our new EUA application. If made or that the FDA does determine to review the new EUA application that the submitted materials will satisfy the performance criteria and other FDA review standards in requirement that are being considered and applied by the FDA.

Regarding the pursuit of 510(k) clearance from the FDA for the DPP SARS-CoV-2 antigen system. These clinical trials are also ongoing. The timeline for the trials and our achievement of related milestones were delayed by the evolving U.S. populations with low COVID-19 positivity rates triggered by vaccination rollouts, the impact of those evolving populations on the rate of enrolling subjects, the absence of guidance from the FDA regarding how to treat low positivity rates within a clinical study and the FDA's as yet unissued 510(k) guidance regarding COVID-19 antigen tests. On July 20, 2021, BARDA amended the \$12.7 million contract in order to subdivide effective retrospectively certain previously specified milestones with respect to the clinical trials for the DPP SARS-CoV-2 Antigen system in order to reflect the effects of this delays we experienced in the clinical trials, which were outside of our control.

As of June 30, 2021, we had achieved certain of the newly defined milestones. We've begun to incorporate into the 510(k) clinical trials, foreign source samples similar to the planned way resubmission for the DPP SARS-CoV-2 Antigen system with the objective of mitigating the impact of low COVID-19 positivity rates resulting on the vaccination rollout in the United States.

We are confident we have the capability to produce the data required for permanent regulatory approval. This pursuit represents our commitment to the point of care testing market over the long term. The final component of our internally developed COVID testing portfolio is our antibody test. We believe that the global proliferation of COVID-19 vaccination programs may create opportunities for the DPP COVID-19 IgM/IgG system.

We continue to pursue those opportunities at regions where the test has been approved.

However, policies of individual countries are related to the monitoring of viral loads and other use cases or at an early stage, and we are seeing evidence of overcapacity among suppliers of competing tests. These regulatory and market conditions could adversely affect the demand for and pricing of our COVID-19 antibody test outside the United States. Transitioning to our commercial efforts. Throughout 2021, we've been actively pursuing sales opportunities for DPP SARS-CoV-2 Antigen system with government agencies, non-government organizations, and distributors in countries where the test systems is approved and registered."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: BARDA and COVID-19 Tests***

48. Background: Eberly, May 9 2021: "As we've previously outlined, we have received two awards from BARDA for the development and regulatory submissions of both our DPP SARS-CoV-2 Antigen test system, which we will refer to as our COVID-19 Antigen test and the DPP Respiratory Panel."

49. Background: "Chembio Diagnostics Continues US Pivot, Updates SARS-CoV-2 Testing Strategy" The first award was for roughly \$630,000 for the development and receipt of EUA authorization for the COVID-19 antigen test ... The second award totals up to \$12.7 million for the receipt of a 510(k) approval for the COVID-19 antigen test as well as for the development and receipt of EUA authorization for the DPP Respiratory Panel. The DPP Respiratory Panel test system is intended to provide simultaneous, discrete and differential detection of influenza A, influenza B and SARS-CoV-2 antigens from a single patient respiratory specimen, such as a nasal or nasopharyngeal swab. It is expected to provide results in approximately 20 minutes and be run on Chembio's DPP Micro Reader analyzer. The system is intended to enable appropriate clinical management of patients with suspected respiratory infections and assist in the containment of COVID-19 cases during the flu season. The U.S. Centers for Disease Control and Prevention has recognized that contemporaneous testing for the three viruses will



provide public health officials with information to help limit the spread of viruses while conserving scarce resources.

50. Background: Eberly: "On July 20, 2021, BARDA amended the \$12.7 million contract in order to subdivide effective retrospectively certain previously specified milestones with respect to the clinical trials for the Chembio DPP SARS-CoV-2 Antigen system in order to reflect the effects of this delays we experienced in the clinical trials, which were outside of our control."

51. As stated above, What specific delays were outside of Chembio's control? And what specifically were the delays experienced in the clinical trials?

52. Eberly, "As of June 30, 2021, we had achieved certain of the newly defined milestones. We've begun to incorporate into the 510(k) clinical trials, foreign source samples similar to the planned way resubmission for the DPP SARS-CoV-2 Antigen system with the objective of mitigating the impact of low COVID-19 positivity rates resulting on the vaccination rollout in the United States."

53. Background: Eberly March 11, 2021: "Now, I will talk about the DPP respiratory panel, development is progressing well. Again, this is a great example of the versatility of our DPP platform and its ability to multiplex. Differentiating COVID-19 flu A and B can assist healthcare providers and patient management and improved resource utilization. We believe the clinical utility of this test will extend well beyond the pandemic phase of COVID-19 and in the future respiratory

virus seasons. To capitalize on the current demand for our respiratory panel product and leverage our expanded U.S. commercial organization, while our DPP systems are under development, we recently signed an in-licensing agreement to distribute a respiratory panel test. This test is a point-of-care EUA approved respiratory panel for the detection of SARS-CoV-2 antigens, flu A and flu B. We believe, it will complement our COVID-19 portfolio because it will be sold across the same overlapping decentralized markets as our currently available point-of-care HIV tests and other COVID-19 products in development."

54. Why was there a belief between BARDA and Chembio that there was a strong current demand for an In-House Flu A and Flu B product? Who was Chembio planning to sell respiratory panel products to? Who was a supposed prime customer?

55. Did Chembio have to meet certain obligations to BARDA that were clearly not in the best interest of Chembio shareholders fiducially? Did the Board not communicate to Shareholders any obligations the BARDA grant held that were not related to Chembio's bottom line?

56. Background: Eberly June 5, 2021: Our relationship with BARDA has been thoughtful and collaborative throughout this process. Their advice and support has been invaluable, and we look forward to continued partnership between our organizations. Recall from our last quarterly earnings call, our

regulatory goals for the year include: achieving EUA approval and 510(k) clearance for the DPP COVID-19 Antigen test; EUA approval for the DPP Respiratory Panel; and securing authorization for the submitted CLIA Waiver file for the DPP HIV-Syphilis test ... Our previous EUA submission of our COVID-19 Antigen test was not prioritized for review by the FDA. Achieving approvals for the COVID-19 Antigen test and the DPP Respiratory Antigen Panel under the BARDA awards remain a top priority and we are laser-focused on them. The COVID-19 regulatory environment remains dynamic and subject to change ... We are confident that we possess the technical capabilities required to achieve the EUA. As I shared during our last earnings call, given the uncertainty regarding the processes, we will not be providing any status updates or estimated time lines regarding the EUA process. Our work to obtain 510(k) regulatory approval for the COVID-19 Antigen test, with BARDA's support to fund the clinical trials, further evidences our long-term commitments to the point-of-care market. This permanent clearance is in anticipation of when COVID-19 testing is no longer considered an emergency and becomes a standard test used in upper respiratory diagnostics.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: The Effect of Specific COVID-19 Variant-of-Concern Omicron Not Being Potentially as Detectable as Other COVID-19***

***Variants-of-Concern Alpha, Beta, Gamma, and Delta Using Available Diagnostics and the Effect This Had On Chembio's COVID-19 Antigen and Antibody (Serological) Product Development***

57. Chembio never provided records, accounts of contact, or quarterly guidance on how COVID-19 Variants-of-Concern would impact the Company's diagnostic testing capabilities, development, and selling projections, particularly for the Omicron variant.

For reference, the World Health Organization (WHO) has working definitions for SARS-CoV-2 Variant of Interest (VOI) and Variant of Concern (VOC).

A SARS-CoV-2 VOI is a SARS-CoV-2 variant:

- with genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; AND
- that has been identified as causing significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.

A SARS-CoV-2 VOC is a SARS-CoV-2 variant that meets the definition of a VOI (see above) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- increase in transmissibility or detrimental change in COVID-19 epidemiology; OR
- increase in virulence or change in clinical disease presentation; OR
- decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics

[https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)

58. Analyst Joanne Lee May 8, 2022: "All right. Thank you for that. And just as a follow-up regarding the COVID program, could you discuss some of the steps the company has undertaken or planned to carry out to address certain challenges that may have emerged given where we are in terms of COVID cases and the fluctuation that's largely driven by the emergence of a new variant?

Eberly: Yes. What we're seeing is over the last 14 days, we've seen somewhat of a surge in cases and hospitalizations. I just read an article in The New York Times

today about the rates increasing again due to the Omicron variant. So, we're watching that very, very closely. As you know a lot of our revenue in Q4 and Q1 was COVID related. So, we're getting ourselves in a position commercially and from a manufacturing perspective to respond very quickly if testing demand surges whether it's in the United States, whether it's in South America, whether it's in Europe. So, we see it as something as an opportunity if COVID continues to be out there and fluctuate in its positivity rate among the patient population. I think we're in a better position today than ever based on what we were able to do in the first quarter to scale our production and meet the Bio-Manguinhos order which happened to be the largest customer order in the company's history. So, the team here at Chembio did a fabulous job of combining automation capacity manual production where needed to meet that demand. So, if the demand increases where might be I think we're in a good position to help with whatever demand and testing is out there."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: FDA-Required Labeling Changes Related to Numerical COVID-19 Antibody / Serological Testing***

59. Because CEMI's tests were never publicly available per say, what exactly was the text of the Chembio DPP COVID-19 antibody (serological) test

label that was approved by the FDA for EUA from April-May 2020? This record is omitted in the Tender Offer. Since CEMI, FDA, and BARDA said after the EUA DPP antibody (Serological) test rejection that further work would continue with DPP technology for COVID-19 in both antibody (serological) and antigen form, what supposed terminology changes or specificity / sensitivity numbers needed to be quoted in lieu of that on the supposed new label. What was the FDA's template for labeling COVID-19 antibody (serological) and antigen tests before and after the EUA antibody rejection?

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: "Poor Quality" COVID-19 Serological Tests***

60. Eberly stated on May 4, 2020 that was a proliferation of poor quality COVID-19 serological tests in the market, and that the FDA had not reviewed their performance data. To this day, Eberly never followed up with Chembio Stockholders about any FDA communication or Chembio intelligence of the cause, scope, or source of this problem or whether it was resolved. Plaintiff cannot assess whether the "poor quality" was a result of i) poor quality materials, or ii) poor scientific understanding of the virus due to COVID variants (such as Alpha, Beta, Delta, or Omicron to name a few) or lack of genetic sequencing information, etc.

iii) lack of quality control, etc. Further, neither Chembio nor the FDA released any information about the origins, manufacturers, distribution quantities, distributors (courier, website, physical store, etc.), and geographic locations of distribution of these poor quality tests.

61. “There are many recent press reports about the proliferation of poor quality COVID-19 serology tests in the market. And that the FDA has not reviewed their performance data. We recognize that this is causing some confusion and damaging the perception of antibody testing in general.” - Rick Eberly, May 4, 2020

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact, and Allocation of Resources RE: Abandonment of Numerical Antibody and Delays and Abandonment of In-House Antigen Test Sales and Chembio Entering Into An Agreement with Third-Party InBios for the STATUS COVID-19 / Flu A / Flu B Respiratory Panel Test, that was Outside of the Scope of Chembio's Prior Financial Guidance.***

62. What were Chembio's data source(s) for forecasting for the upcoming flu season that made the Flu A and Flu B aspects of the InBios STATUS test so attractive?



63. Why specifically Defendants "haven't really talked a lot about" this out-of-scope product agreement, nor provide any specifics about the financial agreement they entered into with InBios for these tests; so Stockholders can assess the financial impact of this decision, and the reasons this decision was made, until potentially well after the InBios agreement was made.

64. Eberly, Nov 6 2022: "The other thing I would add Per, that we haven't really talked a lot about is that we are now selling a flu product and a respiratory antigen product in the United States. We brand it by the name of Status. So if we do have a flu season and we're beginning to see an uptick in flu incidence in the United States coming up in the south and moving north. So if we do have a pretty typical flu season, we're in a position -- a great position with a flu product, standalone flu product as well as a respiratory antigen product that detects COVID flu A and flu B. So that's where we're moving. Higher value markets, higher average selling prices. And hopefully, that's another long answer to your question, but it's imperative to our strategy as we move into 2023."

65. Chembio did not believe non-numerical tests were of equal use in the context of the COVID-19 pandemic. See "Chembio Submits EUA Application for New DPP SARS-CoV-2 IgM/IgG Test System" Sept. 08, 2020: "The DPP platform's ability to provide objective, numerical results can aid clinicians in avoiding the human interpretation errors associated with visual readings of

traditional lateral flow tests.". Chembio did not provide any specific information as to what made them change their mind.

66. Why did Chembio sign this distribution agreement without first notifying Chembio shareholders about the status of their existing antibody and antigen test development programs, which continued to be in limbo? If the problem of the immediate demand for COVID-19, Flu A, and Flu B was solved amongst Chembio's customer pool, why was development of the antibody and antigen tests not completely halted until regulatory clarity arose, now that an "in lieu of" product was available? Did Chembio have a more significant undisclosed liquidity problem?

67. Chembio must specifically define what is meant by "decentralized" in regards to "overlapping decentralized markets" and/or the "decentralized testing locations across the U.S. and globally"

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact in the Tender Offer RE: Chembio's Extensive Program with CDC on Flu Prior to 2019.***

68. Neil Goldman, Executive & Chief Financial Officer, March 12, 2020: "We do have experience of respiratory products. We have not maybe marketed but we

have a several years ago extensive program with CDC on flu but the product that we are now recommending is really is a screening program based on other product and based on other outbreak we have been in recent outbreaks like Ebola, Zika. So our platform, our analyzer it fit very well because as you may know we are talking about the large population [indiscernible] and we believe that our platform will provide a big value on that. Also the relation goes with Lumira has hopes of value here because they have a experience in respiratory area.”

***Material Nondisclosures Concerning the Lack of Records, Accounts of Contact in the Tender Offer RE: The Company’s Contact with the CDC About Observation of an Extremely Limited Incidence Rate for Influenza A and Influenza B in the U.S. Domestically From Approximately July 2021 through February 2022.***

69. Eberly, 4 March, 2022: "Late in December (2021), the FDA declined to review our EUA application for the respiratory panel. In order to address the near absence of influenza in the United States, the submission had included foreign-sourced, influenza-positive samples, preserved in viral transport media. The notice from the FDA informed us, that in order to proceed, we will need to prospectively collect Influenza A and Influenza B samples, and then submit a new EUA

application. Given the continued near-absence of influenza in the United States, we were unsure the timeline and the ability to complete the necessary trial."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Chembio's Zika Virus Projects with BARDA***

70. What specific scientific factors quantified success for prior BARDA Zika virus DPP projects with Chembio? What specifically was it about the Zika virus DPP product that qualified it to be a basis platform for a COVID-19 antigen or antibody/serological test? Why would the costs and profit margins associated with a Zika test translate to a COVID-19 antigen test? Why was the Zika DPP product considered a stepping stone to the COVID-19 antigen test?

71. Background: Chembio received grant monies from BARDA not soon after the FDA denied Chembio's EUA for their DPP COVID-19 finger-prick blood antibody (serological) test in June 2020. Based on various pieces of on-the-ground scientific intelligence, and including Chembio and BARDA's interest in testing for other respiratory viruses, BARDA and Chembio became developing an antigen COVID-19 nasal swab test with grant monies. Chembio separately continued development of the finger-prick blood test, best plaintiff can tell. This curiously timed financially-shoring up measure for Chembio by BARDA was

attributed by Chembio to previously funded “successful” BARDA Zika virus DPP projects with Chembio.

72. Eberly, March 12, 2021: "Again, I wanted to reiterate that we appreciate the FDA's guidance and BARDA's continued support of our COVID tests. And we are committed to gathering the specific information required. We were competent. "

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact, and Itemization of Revenue and Expenses in the Tender Offer RE: Other Infectious, Fever, and Respiratory Diseases***

73. Zika virus products, Cervid TB products, Elephant TB products, Chagas products, ZCD products, Dengue products, Chikungunya products, and Leishmaniasis products motioned in the Chembio Investor Relations Investor Deck Corporate Presentation dated January 2023.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Multiple Phase Projects with Shire Human Genetic Therapies, a subsidiary of Takeda Pharmaceuticals and/or any other Takeda subsidiaries.***

74. Chembio claimed “the nature of the program” “limited” what could be said about the program, and then left Chembio shareholders in the dark to this day.

75. Analyst Per Ostlund, August 9, 2020: Okay, that's fair as well. One last question for me. I suspect there's not going to be a lot you can say to elaborate on the second Takeda program, but clearly, that's interesting to see that another one has gotten its way into the hopper. I guess the question is, can you say anything about it, whether it's a program type duration size, that sort of thing? And then maybe secondarily, just how much of that was catalyzed by the successful initial development of the first.

Eberly: Yes, Per. I think one of the things we're proud of is that certainly, the second program is building off the success of the first program in the collaboration we had with the Takeda team. So we're delighted to announce the second program due to the nature of the program and the confidentiality of it, we're limited in terms of what we can say about the scope of the program, the biomarker and any funding levels. But we're certainly excited to take on the second program with Takeda, and I think it really demonstrates the capability, the DPP technology and the platform and the ability to drive enhanced sensitivity and specificity in a point-of-care asset.

76. Analyst Bruce Jackson, March 12, 2020: Okay. Fair enough. And then last question, you've got several programs ongoing in the companion diagnostics area. Anything news report on any of those programs?

Eberly: Yes. We don't have any news to report on that at this point. We do have some ongoing work in that area.

Bauser: Okay. Thanks. And then just lastly here can you walk us, sorry?

Gail Page: Sure. Go ahead.

Kyle Bauser: Can you just walk us through related to the Takeda partnership? So the feasibility is done. Can you speak about what the next phase of this project entails? And you mentioned it triggered a subsequent tranche of funding. Can you speak to the level of capital that was triggered?

Gail Page: So I'm going to refer that to Javan who is our chief technology officer and Javan will just give a brief comment on the next phase of development.

Javan Esfandiari: Hello this is Javan. We basically have as we made the press release we completed the feasibility and we are now in the phase 2, the full

development program. That's what it is and as soon as we complete development, free to design then we would move to validation and verification.

Bauser: Okay. Then the level of funding for the tranche? I don't know if I got that.

Neil Goldman: Yes, Kyle as you may remember from previous newer programs going back over the last year and a half or two we've gotten away from disclosing those amounts for competitive reasons.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Outcome of Important Projects with AstraZeneca's Respiratory Disease Division***

77. John Sperzel, Nov 19, 2019: In collaboration with AstraZeneca, we successfully developed a quantitative point-of-care diagnostic test to identify eosinophilic respiratory disease and obtain the first regulatory approval, a CE mark. The preclinical studies have also been completed and we view the completion of both product development and preclinical as important milestones.



Analyst Bruce Jackson : "I was wondering if you'd be willing to give us a quick update on the status of the AstraZeneca companion diagnostics test. And the syphilis combination test with the FDA."

Sperzel: "So, I'm obviously a little bit restricted in what I can say about AstraZeneca. So what I said in the prepared remarks is about, what I can say about it. In terms of HIV syphilis we continue to be optimistic about getting that before the end of the year. We're excited for that to happen. Our sales team is trained. And ready to hit the ground running. Once we get the green light from the FDA. Data that we have looks excellent. But I don't want to dig too much into that, while the review process is ongoing. I don't think that, that's fair to the agency."

78. Eberly, 4 May, 2020: "We continue to make progress with our collaborators AstraZeneca and Takeda Pharmaceuticals. As you can imagine, these entities are also discovering their new needs as it relates to testing for COVID-19. In their trials and this could present an entirely new opportunity for Chembio. The technical feasibility study in collaboration with Takeda has been completed. Incremental funding has been provided for the next phase of the program. Now, I'll turn the call over to Neil, for the details of our first quarter financial performance."

79. Analyst Bruce Jackson, 9 August, 2020: "In terms of the new test that we - so in terms of the other new tests you've been watching out for the

eosinophilic test for the asthma that you've been working with AstraZeneca. What's the status of that program?

Eberly: Yes, Bruce, if you go and take a look in our first quarter 10-Q, and you'll see this again in the table in the second quarter Q, in the MD&A section. We have tables where we talk about the various products in development. And you'll see there's some documentation there that, as you said, the test has gotten through the process went from 0 to CE Mark inside of 12 months. And is now available for research use only. And that's similar to - described around Takeda. That's all that - what else we can say about it at this time.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Revenue and Technology Sharing Agreement with LumiraDX***

80. The details of who was responsible for what in this agreement. Especially regarding intellectual property. What was Lumira's existing benefit to Chembio? If it was experience, a distribution network and prime partners as alluded to, who exactly were these skilled workers and who were the partners or distribution network? Were they primarily government or public partners? What

was the revenue mix of domestic vs. foreign coming from LumiraDX's existing partners that applied to Chembio?

81. Analyst Bruce Jackson August 9, 2020: Okay. And then, just a quick question on LumiraDx. Can you comment at all on how that program is moving along? And if you can provide any other details on the types of things that you're working on, that would be great.

Eberly: Yes, Bruce, as we announced, the Lumira agreement was a strategic relationship. So given the fact that Lumira is a private company (NOTE: later went public and later declared Chapter 11 Bankruptcy), and we can't speak to their development program. We're very limited in terms of what we can say. But generally, Bruce, we've had a very, very positive, strong collaboration with LumiraDx. And so we continue to move forward in that strategic relationship. And we're hopeful that we'll continue to be in that relationship."

82. Analyst Kyle Bauser, March 12, 2020: "So I'll start off with the partnership with Lumira DX. How long can we anticipate taking to develop a test and then subsequently to get the okay from the FDA? Maybe you can just kind of walk us through timelines and next steps here?

Gail Page: I certainly do the best I can Kyle. As far as timing I think the only thing we're prepared to comment on today is obviously we believe bringing the two organizations together where really prepared this and it will be done very expeditiously. Obviously we have been doing some feasibility work and monitoring and measuring things as they have developed.

So it's our goal to obviously bring something to the market as soon as possible but we want to bring something that commercially viable, something that can make a difference and it's not just noise in the market. Does that help you?

Kyle Bauser: Yes. That's helpful and just following up on that so of course the DPP platform seems perfect for an accurate test here as it relates to COVID-19 but can you talk about what Lumira will provide in this partnership? I know in the previous partnership for infectious disease testing they provided funding but it looks like they're going to be utilizing their own platform as well. So how does the partnership look and kind of who's doing what?

Gail Page: Sure. So obviously we bring a lot of scientific expertise to the table as LumiraDX and we brought this together so that we can put our collective intelligence together. They have a tremendous distribution network and this is the case where it is a strategic partnership and we built it in the spirit of the win-win so

that both sides are properly incentivized and rewarded. Our goal is to bring the products to market on both platforms and LumiraDX will sell DPP and their own platform. We will -- I think it's in the 8k we'll talk a little bit more about as we further develop the program but this is really a program where it is in the spirit of the true strategic partnership.

Bauser: Sure. Okay. Thanks and any to the extent you can share, I mean any estimates to how much of your own capital you'll be committing to COVID-19 and further you are talks with local governments or foundations for grants around this test?

Gail Page: Yes, certainly in the discussions but obviously our working capital is very precious to us. So we understand that. Now I think the point out here that's important is our box does have clearance and there's test labs [indiscernible] mark so when you think about it there's the best of this world here with all the products that we can develop and that we have on the table and there is obviously component to this where Lumira is funding the development on their box. "

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: HIV/Syphilis CLIA Waiver***

83. Related to the Tender Offer's lack of records about any specific financial projections of "tremendous growth" in The United States, resulting from Chembio's HIV/Syphilis CLIA Waiver with the FDA.

84. Defendant Eberly does not quantify "growing exponentially" as it relates to Syphilis in the United States and Craig-Hallum does not account for this supposed exponential growth in their projections.

85. Does not provide specific documents from the FDA and CDC regarding why a product that is WHO certified or approved, or European CE Marked and Visa approved in Brazil is of regarding abbreviated clinical trials crucial to the timely success of the HIV/Syphilis test that was delayed many times for various reasons by Chembio.

86. Eberly, November 6, 2022: "And so we are in the early stages of discussions with the FDA and the CDC on how we can accelerate an abbreviated clinical trial in 2023 to get that OTC product for HIV onto the market in the US. So we are going after the higher value markets. "

"So the CDC is pushing for additional syphilis testing. Syphilis is growing exponentially in the United States and the CDC is tracking that ... And so we are in the early stages of discussions with the FDA and the CDC on how we can accelerate an abbreviated clinical trial in 2023 to get that OTC product for HIV onto the market in the US."

87. Eberly does not quantify "tremendous interest" as it relates to Chembio's OTC HIV test in the United States by the CDC and Craig-Hallum does not account for this supposed exponential growth in their projections. Defendant Eberly does not state if the \$42 million program mentioned is reasonably attainable by Chembio or what the guidance is.

88. Eberly, 6 November 2022: "Regarding OTC in the United States for our HIV home test or self-test. We're seeing again tremendous interest in the CDC. They just announced I want to say three weeks ago a \$42 million program to make tests available for people to test at home discreetly. And that's what we're seeing the CDC's interested that a lot of times people are reluctant to get tested in a physician's office or urgent care center because it's not discreet. But the home test, the self-test will allow discreet testing for an individual in the privacy of their home.

89. Receipt of the CLIA Waiver was announced by Chembio on Feb 24, 2023, curiously after the Tender Offer. The Tender Offer's financial projections by Craig-Hallum do not include the "tremendous growth" from this waiver.

90. Eberly estimated 250,000 CLIA-waived clinics as a Total Addressable Market for Chembio, but later states "we are going after the higher value markets". Did Chembio have a realistic chance to initially distribute into all of these 250,000 CLIA-waived locations, and if not, why were more specific, non-

inflated projections based on "higher value markets" not included at the time, nor in the Craig-Hallum projections later during the Tender Offer? If not, why did Defendant Eberly not provide more specific financial projections to Chembio Stockholders? Eberly previously disclosed severe manufacturing limitations at Chembio both in manual and automated production lines that makes it seem unreasonable for CEMI to achieve the level of production necessary for selling to all 250,000 CLIA-waived locations. Nor has it been proven that all 250,000 CLIA-waived locations are in need of Chembio's tests.

91. Eberly, May 8, 2022: "Bruce Jackson: Okay. Okay. And then, moving over to the HIV-Syphilis combo test in the CLIA waiver. Can you maybe remind us, what are the remaining steps in the process? And where are we right now?

Eberly: Yes, Bruce. Where we stand today is, as we talked about in the fourth quarter 2021 earnings call, the FDA did request some additional data to supplement our data submission for the CLIA waiver application, and so, we've been in the process of gathering that additional data. And once we're completed, we will submit that to the FDA and then hopefully have a CLIA waiver approval.

Jackson: Okay. And then, would you care to hazard a guess as to when the data might be assembled?



Eberly: Yes, Bruce. It's ongoing. We haven't projected any timing on that or announced any timing on that. And so, that's where we're at. And we're working very, very aggressively and as quickly as possible to get the additional data. And once it's complete, we will submit it to the FDA. And then, we don't know what the turnaround time will be at the FDA, given their workload. So the timing on this is a little bit uncertain Bruce, because of those factors."

92. Eberly, Nov 6, 2022: "So we are really optimistic that once we get CLIA waiver that we'll see tremendous growth in the United States. And the other thing I would say about HIV-syphilis is in the sexually transmitted disease community, one of the reasons the CDC is concerned is they're seeing a growth in co-infections...So the CLIA labs in the United States, we just did some analysis on how many CLIA labs now exist in the United States post-COVID. And it's 250,000 CLIA-waived labs, which are mostly urgent care centers, physician offices and so forth... So we are going after the higher value markets ... On the DPP HIV-Syphilis test, we continue our work to address the FDA's request for additional data to achieve a CLIA waiver ... Our EUA submission for the DPP SARS-CoV-2 antigen test continues to be under active review by the FDA and we are encouraged by the progress made over the past quarters. Late in the third quarter, we announced the company was awarded a \$3.2 million contract from the Centers for Disease

Control for the development and clinical validation of a rapid point-of-care diagnostic test for syphilis."

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact, and Itemization of Expenses in the Tender Offer RE: Chembio's Ebola DPP Antigen (EUA) serological test***

93. Eberly, August 7, 2022: "So there was certainly a clinical need for Zika. The following year, there was an Ebola outbreak. So we developed a DPP Ebola test to help with the outbreak with Ebola, which that product as of today still emergency use authorization in the United States. "

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact, and Itemization of Expenses in the Tender Offer RE: Chembio's exploratory efforts to develop a Lyme DPP serological test***

94. Eberly, 6 November, 2022: "We also announced in the third quarter development of a rapid point-of-care diagnostic test for Lyme disease. Lyme disease caused by the bacterium *Borrelia burgdorferi* is transmitted to humans via infected tick bites. Recently, the CDC has updated its guidelines for Lyme disease

diagnosis with a new algorithm termed MTTT for modified two-tier testing. These two steps are methods that are labor-intensive, take a long time to run and require trained professional laboratory personnel. The DPP Lyme IgM/IgG test is designed to be a rapid multiplex point-of-care test and combine the two-tier testing algorithm into one DPP test cassette, utilizing our DPP Micro Reader II for objective test results ... We are currently collecting preclinical data for our DPP Lyme test in development. We are hopeful this data will underpin a productive pre-submission meeting with the FDA. Our intention is to complete the pre-submission meetings for both the DPP TNT and the Lyme test to discuss guidance on the structure and requirements for potential pivotal clinical trials. I will now hand the call over to Larry to detail the third quarter financials and provide more details on our operational improvements under the Global Competitiveness Program....The other example we talked about today was our DPP Lyme multiplex product, where Lyme is a growing clinical concern in the United States."

***Material Nondisclosures Concerning the Lack of Books, Records, Accounts of Contact, and Itemization of Expenses in the Tender Offer RE: Chembio's exploratory efforts to develop a Mpox (Monkeypox) serological test***

95. Eberly, August 7, 2022: "So we are monitoring the Monkeypox situation very, very closely. We know that globally there's now 26,000 cases in

over 80 countries. In the United States, there's now 6,600 reported cases. So this is a growing problem. We see that as an area where we can provide value, because we have done it for other outbreaks. The interesting thing with Monkeypox is that the symptoms are very similar to other essentially transmitted diseases like herpes and syphilis, as well as other healthcare issues like scabies and eczema. So it's beginning to show like it's a very difficult disease to diagnose, because of a similar symptomology with other viruses. So we are going to monitor this closely. We have a great network of individuals at the NIH, the CDC, as well as BARDA, who funded our COVID test development. So we are in conversations and in consultation with our colleagues at the NIH, the CDC and BARDA, to see what is the need the current tests that are available today for Monkeypox are PCR, which you have to take a sample from the open skin lesions, which is very painful, very difficult to obtain very, very good samples for PCR. So we are monitoring this closely, all options are open for us and if we see there's a growing consistent clinical need and the ability to utilize our product technologies as we did with Ebola, Zika and COVID, we will make a decision and move forward or not."

96. Eberly August 16, 2022: "We are in dialogue with leading health organizations at the federal and state level to evaluate the need for a rapid test to detect and diagnose monkeypox. We are assessing the market needs, timing, regulatory pathway and investment required to develop a test," said Richard

Eberly, Chembio's President and Chief Executive Officer. "Current tests available for monkeypox are PCR based, and given our history of developing rapid POC tests for infectious disease outbreaks, we believe we may be positioned to leverage our technology to provide a differentiated rapid solution. Based on our findings we will determine if this is a viable future opportunity for Chembio."

97. Eberly, Nov 6, 2022: "Relative to other opportunistic disease states, certainly, everyone is aware that today the U.S. Government declared a public health emergency for Monkeypox, the WHO also declared a public health emergency on July 23rd, the States of California and New York and Illinois have followed suit, in terms of declaring a public health emergency."

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: SEC Subpoenas***

98. Details about what precisely what was subpoenaed? Was it communications? Was it financial information? How does Biosynex know this subpoena is not relevant, when there is no publicly available information available, even years later? Can Shareholders get access to this subpoena through a Nondisclosure Agreement (NDA) process?

99. Why was the following non-qualified stock option written at \$1.12 per share out until 2029? What positive sentiment allowed for that, versus the

\$0.45 declared in the Tender Offer? What materially changed between January 5, 2022 and the Tender Offer that resulted in this 59.8% drop in supposed market capitalization of the company. Why was this not included in the Craig-Hallum analysis?

100. Background: Jan 6, 2022: "Chembio Diagnostics Reports Inducement Award Under Nasdaq Listing Rule 5635(c)(4)" Chembio granted to Mr. Steenvoorden on January 5, 2022 a non-qualified stock option (the "NSO") to acquire 300,000 shares of common stock at a price of \$1.12 per share, expiring on January 5, 2029, and a restricted stock unit award (the "RSU") to acquire, without payment of any purchase price, up to 160,714 shares of common stock. Subject to Mr. Steenvoorden's continued service with Chembio, the shares subject to the NSO will vest in four equal annual installments and the shares subject to the RSU will vest in three equal annual installments, except that, in each case, vesting will accelerate in full upon (a) Chembio's termination of Mr. Steenvoorden's employment without Cause, Mr. Steenvoorden's termination of his employment for Good Reason or the expiration of the Term upon notice of non-renewal delivered by Chembio, in each case within twelve months following a Change in Control, or (b) Mr. Steenvoorden's death or Permanent Disability (each such capitalized term as defined in the employment agreement between Chembio and Mr. Steenvoorden).

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: Potential Illegal Naked Short Selling and the Underlying Cause of Millions of Aggregate CEMI Shares Failing-to-Deliver Based on SEC Data On Dozens of Days in Relevant Time Period***

101. Based on other small capitalization NASDAQ companies such as Applied UV, Inc. (NASDAQ: AUVI) and Astrotech Corp. (NASDAQ: ASTC) adopting or reserving the Right to Counsel or Shareholder Rights statements regarding Potential Illegal Naked Short Selling or otherwise suspicious accumulations of stock, and based on the fact the SEC Fails-to-Deliver has no substantive difference in the data schema between AUVI and CEMI (Chembio) or ASTC and CEMI (Chembio), is it possible that illegal naked short selling or suspiciously accumulations manipulated the CEMI share price? All records related to potential investigation of short selling or other suspicious trading activity that resulted in millions of aggregated CEMI shares failing to deliver on dozens of days over the relevant time period is requested.

***Material Nondisclosures Concerning the Lack of Records and Accounts of Contact in the Tender Offer RE: The Craig-Hallum Fairness Opinion***

102. On February 22, 2023 one of the companies Craig-Hallum compared Chembio Diagnostics to for the purposes of Fairness, Lucira Diagnostics, filed for Chapter 11 bankruptcy with a cited reason of a "protracted" FDA review process. Lucira Diagnostics curiously received FDA Authorization of First & Only At-Home Combination PCR COVID-19 & Flu Test, the day after, on February 24, 2023. These facts make Lucira Diagnostics an invalid comparable company for the purposes of Fairness. Further, Lucira Diagnostics is not a comparable company either, because they are engaged in PCR technology to a large extent, unlike Chembio which is only engaged in antibody (serological) and antigen testing. Lucira is a COVID-19 specific company and does not have a diversified portfolio of infectious disease intellectual property and patents as Chembio does. There is reason to believe that comparing Chembio to Lucira is unfair because Chembio has significantly diversified intellectual property including patents and patents pending.

103. OraSure Technologies is not a comparable company to Chembio because OraSure was targeting the US Military market and the Craig-Hellum Fairness Opinion omits this. Chembio was targeting the OTC US market, which is dissimilar. DOD awarded a \$205.2 million contract to OraSure Technologies, Inc., to purchase over-the-counter COVID-19 test kits. Deliveries of the 20.6 million test kits will commence October 2021 and ordering capability will continue until



September 2022. See DoD Awards \$647 Million in Contracts for Over-the-Counter COVID-19 Test Kits (<https://www.defense.gov/News/Releases/Release/Article/2780251/dod-awards-647-million-in-contracts-for-over-the-counter-covid-19-test-kits/>)

104. Co-Diagnostics, Inc. is not a comparable company either, because they are engaged in PCR technology, again unlike Chembio which is only engaged in antibody (Serological) and antigen testing.

105. Biosynex SA, Co-Diagnostics, Inc. is not a comparable company, because it does not trade on the NASDAQ and is illiquid with less than 10,000 shares occasionally trading daily on the French ALBIO exchange. Furthermore, due to potential conflicts of interest with the Merger, this analysis should be excluded by Craig-Hallum.

106. Craig-Hallum failed to do a break out comparison to obvious potential similarly-sized and larger Chembio infectious disease competitors / targets, especially in regard to COVID-19 products, which was "substantially all" of Chembio's efforts for a year. Because COVID-19 EUA is a new product category, in essence, as many comparisons as possible should be made. One example is Quidel's (NASDAQ: QDEL) consumer COVID-19 division, instead Craig-Hallum claimed these similarly-sized companies and larger companies with

potentially similarly sized divisions to Chembio overall were outside of the scope of their analysis. Craig-Hallum should have estimated the contribution of COVID-19 sales to Quidel's business, the size of Quidel's dedicated COVID-19 team in terms of employees and budget, and included that estimate for Chembio's Fairness Opinion. Other examples of companies and institutions with COVID-19 divisions Craig-Hallum omitted for purposes of fair comparisons are: Abbot, Becton Dickinson, Beroni Group, Biomerica, Bio-Rad Laboratories, Fujifilm Europe, iHealth Labs, InBios International (a Chembio partner), LG Chem, LumiraDX (NASDAQ: LMDX, a Chembio partner), Mount Sinai Labs, Nanomix, PerkinElmer, Phadia (Thermo Fisher Scientific, who had certain agreements with Chembio), Qiagen, Qorvo Biotechnologies, SD Biosensor/Roche, SG Diagnostics, Siemens Healthineers, Sorrento Therapeutics (filed for Chapter 11 bankruptcy, but got financing), Thermo Fisher Scientific, University of Arizona Genetics Core for Clinical Services.

NOTE: The rest of text in this section "Concerning Preparation of the Projections" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

107. A financial advisor's fairness opinion is one of the most important process-based underpinnings of a board's recommendation of a

transaction to its stockholders. In particular, when a financial advisor's endorsement of the fairness of a transaction is touted to stockholders, not just the analyses used by that advisor to arrive at the fairness opinion, but also the key inputs and assumptions used in those analyses must be fairly disclosed.

108. Here, the Fairness Opinion of Craig-Hallum improperly failed to disclose certain key inputs and assumptions underlying the analyses on which it was based, which renders it misleading. Without this information, as described below, Chembio Stockholders are unable to fully understand Craig-Hallum's analyses and, thus, are unable to determine what weight to place on the Fairness Opinion in deciding whether or not to tender their shares. This omitted information, if disclosed, would significantly alter the total mix of information.

109. With respect to Craig-Hallum's Analysis of Comparable Publicly Traded Companies, the Recommendation Statement states:

Craig-Hallum reviewed and compared certain publicly available financial data, ratios and trading multiples for six comparable publicly traded companies that Craig-Hallum determined, based on its professional judgment, to be reasonably comparable to the Company. The comparable publicly traded companies Craig-Hallum selected were Biosynex SA, Co-Diagnostics, Inc., Lucira Health, Inc., Lumos Diagnostics Holdings Limited, OraSure Technologies, Inc., and Trinity

Biotech plc. Although none of the six selected publicly traded companies are directly comparable to the Company, Craig-Hallum reviewed these companies because, among other things, Craig-Hallum determined that their businesses, financial information, service offerings, and operating profiles are reasonably comparable to those of the Company for purposes of this analysis. In selecting comparable public companies, Craig-Hallum focused on healthcare diagnostic companies focused on infectious diseases with enterprise values below \$500 million. Financial data of the selected companies was based on publicly available information such as public filings and third-party equity research reports. Craig-Hallum reviewed data, including stock price, market capitalization, enterprise value, gross margin percentage, and revenue multiples based on the last 12 months revenues, estimated calendar year 2022 revenues, and estimated calendar year 2023 revenues, for each of the selected publicly traded companies. The multiples for each of the selected companies were calculated using their respective closing prices on January 27, 2023 and were based on the most recent publicly available information and information collected from S&P Capital IQ. The following tables reflects the results of this analysis...”

110. Notwithstanding, however, that the “enterprise value” of each of the six companies selected by Craig-Hallum for its Analysis of Comparable Publicly Traded Companies was a key input in the multiples disclosed in the table

in the Recommendation Statement, Craig-Hallum failed to disclose the “enterprise value” of any of the six companies selected, or the “EV/LTM Revenue,” “EV/2023E Revenue,” and “EV/LTM Gross Profit” multiples for any of the six companies selected. Given that the analysis involved only six companies, the Recommendation Statement should disclose the “enterprise value,” and relevant multiples for each of the six companies selected.

111. Further, when disclosing the “implied equity prices per share” ranges for the Company, the Recommendation Statement fails to disclose how Craig-Hallum (i) derived the “2023E Revenue” for the Company against which the derived multiples were applied (i.e., was it based on the Projections? Analyst estimates?), and (ii) calculated the number of shares of Company common stock used in the “per share” calculations (i.e., as of what date? fully diluted?).<sup>1</sup>

112. With respect to Craig-Hallum’s Analysis of Comparable M&A Transactions, the Recommendation Statement states:

The Proxy disclosed that, as of February 8, 2023, there were (i) 36,725,858 issued and outstanding Shares, including Shares in respect of vested Company RSUs (as defined below), (ii) 3,657,163 Shares covered by Company Options (as defined below), and (iii) 1,570,779 Shares covered by unvested Company RSUs.

Craig-Hallum performed a precedent transactions analysis, which is designed to imply a value of a company based on publicly available financial terms for selected transactions.

Craig-Hallum reviewed and compared certain publicly available transaction valuation metrics that Craig-Hallum determined, based on its professional judgment, were reasonably comparable to the proposed Merger.

Craig-Hallum reviewed and selected precedent transactions that, in the exercise of its professional judgment, were deemed to have similar characteristics to the Company's business and financial profile that had closed or were announced but had yet to close, since January 1, 2018. The following tables reflects the results of these analyses with respect to comparable transactions..."

113. The table in the Recommendation Statement, however, identifies only five comparable transactions. Moreover, the table does not disclose the "EV/Revenue" multiples for any of the transactions, or the EVs (i.e., enterprise values) for any of the targets in any of the transactions. Given that the analysis involved only five comparable transactions, the Recommendation Statement should disclose (i) the EVs for each of the five targets, and (ii) the "EV/Revenue" multiple for each of the five comparable transactions. Finally, the Analysis of Comparable M&A Transactions fails to disclose how Craig-Hallum calculated the

number of shares of Company common stock used in the “per share” calculations (i.e., as of what date? fully diluted?; see footnote 1 *supra*).

114. With respect to Craig-Hallum’s Discounted Cash Flow Analysis, the Recommendation Statement also fails to disclose the number of fully diluted shares of Company common stock used in connection with the relevant “per share” calculations. The Recommendation Statement also fails to adequately disclose how Craig-Hallum determined that a discount rate range of 16.0% to 22.0% was appropriate. The explanation in the Recommendation Statement that Craig-Hallum derived that range based on the “estimated weighted average cost of capital” of the Company is insufficient since it does not disclose the risk free rate, U.S. equity premium, and beta adjustments that Craig-Hallum used.

115. If the discount rate ranges used by Craig-Hallum were artificially high, it would have depressed the value ranges generated for the Company’s shares. See *In re Topps Co. S’holders Litig.*, 926 A.2d 58, 76 (Del. Ch. 2007) (raising discount rates drives down the resulting value range). As such, Chembio Stockholders are entitled to further disclosure concerning the inputs that Craig-Hallum used to determine the discount rate ranges. See *Topps*, 926 A.2d at 76 (subjective judgments regarding discount rates are not scientific, “but highly-paid valuation advisors should be able to rationally explain them.”). Such information is material since a discounted cash flow analysis is “arguably the most

important valuation metric.” Laborers Loc. 235 Benefit Funds v. Starent Networks, Corp., No. CIV.A. 5002-CC, 2009 WL 4725866, at \*1 (Del. Ch. Nov. 18, 2009).

***Material Nondisclosures Concerning Preparation of the Projections***

NOTE: The text in this section "Concerning Preparation of the Projections" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

116. When itemizing the reasons that the Board recommended that Chembio Stockholders tender their shares, the Recommendation Statement states that the “Board considered certain financial projections for the Company prepared by the Company’s management, which reflected certain assumptions of the Company’s management.” The Recommendation Statement further states that “in connection with the Company’s 2022 strategic planning process, [Biosynex’s] due diligence process, and the Company Board’s evaluation of the Offer, the Merger Agreement and the Transaction, the Company’s senior management prepared financial projections for fiscal years 2023 through 2027 (the “Projections”). These Projections were provided to the Company Board, Craig-Hallum and [Biosynex] in preparation for their analysis and evaluation of the Company and its businesses.”



117. The Proxy fails to disclose, however, when (i) the Company's management prepared the Projections, (ii) such Projections were presented to the Board for review and approval, and (iii) the Board approved the Projections for use by Craig-Hallum in connection with preparing the Fairness Opinion. While the Recommendation Statement states that the Projections were "initially prepared in connection with the Company's 2022 strategic planning process," the narrative in the "Background of the Offer" section of the Recommendation Statement fails to identify at what point during the strategic planning process the Projections were prepared. As such, the inference arises that the Projections may have been prepared in close proximity to preparation of the Fairness Opinion by Craig-Hallum, and thus that the Projections were created solely to justify the fairness of the Merger Consideration, and did not accurately represent the standalone prospects of the Company.

118. Supporting the inference that the Projections did not accurately represent the standalone prospects for the Company is an estimate in the Projections of \$31.4 million in revenue for the entire 2023. Yet, on the Company's Q3 2022 earnings call held on November 6, 2022, Defendant Steenvoorden reported total revenue of \$11.2 million for the three months ended September 30, 2022 alone. In response, Per Ostlund, an analyst at Craig-Hallum, stated:

I'm going to start out with the Q3 revenue number. Candidly, I was pleasantly surprised here. I had been sort of – while not officially having an estimate, we have talked and you've talked about the second half being lighter than the first half. And I kind of assume that with a couple of contracts being fulfilled earlier in the year that, we would see a sequential step down. So I was happy to see that number be so strong here in the quarter. Was there anything unusual as far as a bolus of order stocking order somewhere that wouldn't otherwise recur, or was this simply a function of the growing depth of product and geography that you are – you have at your disposal?

119. Defendant Eberly responded that the strong revenue numbers in Q3 2022 reflected successful implementation of a strategy to diversify the Company's business in multiple regions, including “tremendous growth in the United States” and “good contribution from Europe”:

Yeah, Per. Thank you for that question, and I'm glad you were happily surprised. As we've talked over the last several quarters, our strategy has really been to diversify the business by region and by product, it become less dependent on large government tenders, or large government orders, whether they come from Brazil, as we've experienced over the last year or Global Fund countries in Africa. So this quarter, I think was a good indication that we're getting good balanced revenue

from tremendous growth in the United States from our sales team and the investment we've made in the US.

South America same thing. Our balanced attack in Brazil now is beyond COVID. We're focused on our core products in Brazil. And our strategy in Brazil is multifaceted. Not dependent upon the government or Ministry of Health or Bio-Manguinhos. We now have a retail strategy, where our pharmacy partners are now selling our SURE CHECK HIV self-test online on their websites, as well as an e-commerce platform we've set up. So that's a retail strategy. Our other strategy in Brazil is now going out to the states and local, areas like Rio and Sao Paulo, to work with the state and city governments, where they're putting together programs, as well for rapid testing.

And then we're going into the traditional markets in Brazil as well through our distribution partner in Brazil, who calls on hospitals and clinics and so forth throughout the country. So I would say, it's a balanced approach strategically. We continue to maintain excellent relationships, with the Ministry of Health, as well as Bio-Manguinhos in Brazil. So we're working with them on a well-detailed forecast for 2023.

And then over to Europe. I think we're beginning to see, the fruits of a strong investment in our distribution partner in France, who now is in almost every

Western European country in 35,000 pharmacies with our HIV SURE CHECK products. They're launching into new Eastern European countries. We're talking about a Middle East strategy, as well for that product. So we're getting good contribution from Europe.

And then in the UK, we've invested time and energy with our distribution partner in the UK, to get Amazon up and running as well as the Boots Pharmacy. It's now on the shelf in the UK through our pharmacy partner in the UK. So I think it's a long-winded answer Per, but I think we're beginning to see a really good distribution of product revenue in our core products, as well as by regions around the world where in the history of Chembio, they were largely focused on Africa and Southeast Asia, where there's tremendous pricing pressure, tremendous competition from the South Asian manufacturers of rapid tests. So that's where we're at.

120. Additionally, the Proxy itself states that on “November 3, 2022, the Company issued a press release in which it reported revenues of approximately \$39.2 million and a net loss of approximately \$22.4 million for the nine months ended September 30, 2022.” Thus, the reported revenue in the nine months ended September 30, 2022, is approximately 25% higher than the revenue projected for the entire 2023 in the Projections.

121. In sum, in order to weigh for themselves the credibility of the Projections used by Craig-Hallum to prepare the Fairness Opinion when deciding whether to tender their shares, Chembio Stockholders are entitled to disclosure concerning (i) when during the strategic planning process the Projections were prepared by Company management, and (ii) when during the strategic planning process the Projections were reviewed and approved by the Board for use by Craig- Hallum in preparing the Fairness Opinion. Absent such disclosure, the inference arises that the Projections represent depressed estimates created not in the ordinary course of business, but solely for the purpose of justifying the fairness of the Merger Consideration.

***Material Nondisclosures Concerning the Strategic Committee***

NOTE: The text in this section "Concerning Preparation of the Projections" was copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

122. The Recommendation Statement discloses that during May 2022, “Mr. Eberly solicited input from and provided the members of the Company Board and the Business Strategy Committee of the Company Board (the “Strategic Committee”) with periodic updates regarding Project Cheetah throughout the

process.” The Recommendation Statement further discloses that through July 19, 2022, Craig-Hallum updated the Strategic Committee concerning its outreach to counterparties for a potential transaction.

123. The Recommendation Statement does not disclose, however (i) the members of the Strategic Committee, (ii) whether the formation of the Strategic Committee was prompted by a potential conflict, (iii) what powers were granted to the Strategic Committee by the Board in connection with review of potential transactions, and (iv) whether the members of the Strategic Committee were paid any compensation in connection with their service on the Strategic Committee. Such disclosure is necessary to determine (i) the nature of the potential conflict, if any, that prompted the formation of the Strategic Committee, (ii) whether the Strategic Committee at any point exceeded its powers in connection with the performance of its work, (iii) any potential conflicts of the members of the Strategic Committee, and (iv) whether the compensation, if any, paid to members of the Strategic Committee created a potential conflict. Additionally, the Proxy discloses that Craig-Hallum last presented to the Strategic Committee on July 19, 2022, but then fails to disclose whether the Strategic Committee was subsequently disbanded, and if so, for what reason.

### **CLAIMS FOR RELIEF**

NOTE: The text in the sections "Count I", "Count II", and "Count III" were copied directly from SHOLOM KELLER v. CHEMBIO DIAGNOSTICS, INC., et. al. Filed 02/17/23 Case No. 1:23-cv-01388 in the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK.

**COUNT I**

***Against All Defendants for Violations of Section 14(e) of the Exchange Act***

124. Plaintiff incorporates and repeats each and every allegation above as if fully set forth herein.

125. Section 14(e) of the Exchange Act provides that it is unlawful “for any person to make any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made, in the light of the circumstances under which they are made, not misleading . . . in connection with any tender offer or request or invitation for tenders, or any solicitation of security holders in opposition to or in favor of any such offer, request, or invitation.” 15 U.S.C. § 78n(e).

126. Defendants disseminated the Recommendation Statement to Chembio Stockholders recommending that Chembio Stockholders tender their shares to Biosynex in connection with the Tender Offer.

127. By virtue of their positions within the Company, and/or roles in the process of preparing, reviewing, and/or disseminating the Recommendation Statement, Defendants were aware of their duty not to make false and misleading statements in the Recommendation Statement, and not to omit material facts from the Recommendation Statement necessary to make statements made therein—in light of the circumstances under which they were made—not misleading.

128. Yet, as specified above, in violation of Section 14(e) of the Exchange Act, Defendants knowingly or recklessly (i) made untrue statements of material fact in the Recommendation Statement, and (ii) omitted material facts from the Recommendation Statement necessary to make statements therein—in light of the circumstances under which they were made—not misleading, in order to induce Chembio Stockholders to tender their shares in the Tender Offer, and thereby maximize their own personal gain by (i) converting their Chembio shares into cash through the immediate sale of all of their Chembio shares for cash, (ii) the immediate conversion of their Chembio equity-based awards into cash, and (iii) the potential receipt of “Change in Control” payments (as detailed in the sections of the Recommendation Statement entitled “Arrangements with Current Executive Officers and Directors of the Company” and “Potential Change in Control Payments to Named Executive Officers”).



129. The material misrepresentations and omissions in the Recommendation Statement specified above are material insofar as there is a substantial likelihood that a reasonable Chembio Stockholder would consider them important in deciding whether to tender their shares. In addition, a reasonable Chembio Stockholder would view disclosures of the omitted facts specified above as significantly altering the “total mix” of information made available to Chembio Stockholders.

130. Because of the material misrepresentations and omissions in the Recommendation Statement specified above, Plaintiff and other Chembio Stockholders are threatened with irreparable harm insofar as Plaintiff and other Chembio Stockholders will be deprived of their entitlement to make a fully informed decision as to whether to tender their shares in connection with the Tender Offer if such material misrepresentations and omissions are not corrected prior to the Expiration Date. Therefore, injunctive relief is appropriate.

## **COUNT II**

***Against All Defendants for Violations of Section 14(d) of the Exchange Act and***

***17 CFR § 240.14d-101***

131. Plaintiff incorporates and repeats each and every allegation above as if fully set forth herein.

132. Section 14(d)(4) of the Exchange Act provides that it is unlawful “[a]ny solicitation or recommendation to the holders of such a security to accept or reject a tender offer or request or invitation for tenders shall be made in accordance with such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.” 15 U.S.C. § 78n(d)(4).

133. 17 CFR § 240.14d-101 (addressing the contents of a Schedule 14D-9 recommendation statement) provides that Item 8 of a recommendation statement shall “[f]urnish the information required by Item 1011(b) and (c) of Regulation M-A (§ 229.1011 of this chapter).

134. 17 CFR § 229.1011(c) provides for the furnishing of “additional material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not materially misleading.”

135. As set forth above, Defendants knowingly or recklessly omitted material facts from the Recommendation Statement necessary to make statements therein—in light of the circumstances under which they were made—not

misleading, in order to induce Chembio Stockholders to tender their shares in the Tender Offer, and thereby maximize their own personal gain. Accordingly, Defendants have violated Section 14(d)(4) of the Exchange Act and 17 CFR § 240.14d-101.

### **COUNT III**

#### ***Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act***

136. Plaintiff incorporates and repeats each and every allegation above as if fully set forth herein.

137. The Individual Defendants acted as controlling persons of Chembio within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their positions as officers and/or directors of Chembio, and participation in, and/or awareness of Chembio's operations, and/or intimate knowledge of the contents of the Recommendation Statement filed with the SEC, they had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Chembio with respect to the Recommendation Statement, including the content and dissemination of the various statements in the Recommendation Statement that Plaintiff contends are materially false and misleading, and the omission of material facts specified above.

138. Each of the Individual Defendants was provided with or had unlimited access to copies of the Recommendation Statement and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected. In particular, Defendant

Steenvoorden personally signed the Recommendation Statement.

139. Each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of Chembio, and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations alleged herein, and exercised same. In particular, the Recommendation Statement at issue references the unanimous recommendation of the Board to approve the Merger, and recommend that Chembio Stockholders tender their shares pursuant to the Tender Offer. The Individual Defendants were thus directly involved in the making of the Recommendation Statement.

140. In addition, as the Recommendation Statement sets forth at length, and as described herein, the Individual Defendants were involved in negotiating, reviewing, and approving the Merger. The Recommendation Statement purports to describe the various issues and information that the Individual Defendants reviewed and considered in connection with such negotiation, review

and approval. The Individual Defendants thus directly participated in the drafting of the Recommendation Statement.

141. By virtue of the foregoing, the Individual Defendants have violated Section 20(a) of the Exchange Act.

142. As set forth above, the Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Section 14(d) and Section 14(e), by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, these defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Individual Defendants' conduct, Plaintiff will be irreparably harmed.

143. Plaintiff has no adequate remedy at law. Only through the exercise of this Court's equitable powers can Plaintiff be fully protected from the immediate and irreparable injury that

Defendants' actions threaten to inflict, and can Plaintiff and other Chembio Stockholders make an informed decision about whether to tender their shares pursuant to the Tender Offer.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment and relief as follows:

- A. Preliminarily and permanently enjoining Defendants and their counsel, employees and all other agents and persons acting in concert with them from proceeding with, consummating, or closing the Merger, unless and until Defendants disclose and disseminate to Chembio Stockholders, via Non-Disclosure Agreement ("NDA") if needed, the material information specified above that has been omitted from the Recommendation Statement, and correct any false and misleading statements in the Recommendation Statement;
- B. Preliminarily and permanently enjoining Defendants and their counsel, employees and all other agents and persons acting in concert with them from proceeding with, consummating, or closing the Merger, unless Plaintiff receive and deemed satisfactory Freedom of Information Act (FOIA) responses from government agencies closely involved with Defendants: namely the FDA, the CDC particularly the Office of BARDA, The Department of HHS, the DHA or any other DoD branch involved with Chembio, the VA, or any other Federal government agency deemed potentially appropriate by Plaintiff. FOIA requests, especially regarding FDA EUA and 510K submissions can take 18-20 months to receive a FOIA response. The aforementioned agencies denied plaintiffs initial request for expedited processing in all cases, despite plaintiff claiming dangers to human life due to the various viruses and disease

conditions Chembio tests for. Aforementioned agencies denied plaintiffs requests to waive fees, as well, resulting in potentially prohibitively expenses to Plaintiff due to the magnitude of records about Chembio's diversified operations. Plaintiff plans to negotiate with the agencies to determine the limits of information search. Plaintiff needs time to assess with these agencies the simplification process of the FOIA and the feasibility of what is the most important information to convey to Plaintiff. Plaintiff assumes filing additional counter requests before fully satisfied. Plaintiff must assess any exemptions claimed. FOIA requests required to obtain vital information about Chembio's business practices potentially excluded by Chembio are complex due to their diversified portfolio and long timelines of involvement with the agencies. These FOIA responses, Plaintiff believes will help illuminate the material information specified above that has been omitted from the Recommendation Statement, serve to cross-examine Defendants, and correct any false and misleading statements in the Recommendation Statement; if not information is not provided by Chembio Diagnostics as set forth in Sub-Section A of this Section "Prayer for Relief".

C. Rescinding, to the extent already implemented, the Merger Agreement or any of the transactions contemplated thereby, or granting Plaintiff rescissory damages.

D. Directing Defendant to account to Plaintiff for all damages suffered as a result of their misconduct.

E. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' fees and expenses; and

F. Granting such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury on all claims and issues so triable.

Dated: March 7, 2023

A handwritten signature in black ink, appearing to read "David S. Gross", written in a cursive style.

By: /s David S. Gross

David S. Gross

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*Plaintiff*